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EXAMINER

YOUNG, RACHEL T

ART UNIT

PAPER NUMBER

3771

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/576,602	Applicant(s) MARQUE ET AL.	
	Examiner RACHEL T. YOUNG	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/2/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/20/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Preliminary Amendment

1. This office action is responsive to the preliminary amendment filed on 1/2/2007. As directed by the amendment: claims 4-7, 9-10, and 13-15 have been amended, no claims have been canceled, and no new claims have been added. Thus, claims 1-16 are presently pending in the application.

Foreign Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "hub (1') in claim 1, line 4 and throughout the claims must be shown or the feature canceled from the claims. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

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is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign mentioned in the description: "hub1' " on page 4, line 25 and throughout the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to because reference character 26 is called a "fictitious cylinder" on page 2, line 25 and a "butt-joining cylinder" on page 2, line 29.

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The language should be consistent. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

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The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

7. The abstract of the disclosure is objected to because in lines 1, 3, 5, and 7 applicant recites "said", which is claim language that should not be in the abstract.

Correction is required. See MPEP § 608.01(b).

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 1, line 8 recites "balance point", which appears in the specification, but is not defined.

Claim Objections

9. Claims 1, 6 objected to because of the following informalities: Claim 1, line 8 recites "clipped". Quotations should not be used. Claim 6, line 3 recites "3D". Quotations should not be used. Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not

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described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation. Claim 1, line 10 recites "the immobilization strap (5) for holding the patient's mouth closed". The mouth cannot be held shut by this strap because the lips are not controlled by the chin.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, line 3 recites "in any other location", which makes it unclear as to what other location is being referred to and is indefinite language. Claim 1, lines 3-4 recite "or for any other medical or non-medical application", which makes it unclear as to what other application applicant is referring to and is indefinite language. Claim 1, line 4 recites "comprising in particular", which makes it unclear as to if applicant is claimed more than a hub or just a hub. Claim 1, line 6 recites "characterized in that", which makes it unclear as to if applicant is claiming "device for retaining a respiratory mask", "non-invasive mechanical ventilation", "hub", and "shell". Claim 1, line 7 recites the indefinite language "the simple and fast unfastening snap-fastener type", which is unclear as to what structure the applicant is trying to claim. Claim 1, lines 9-10 recite "as well as", which is unclear as to the reference that applicant is referring to that is being claimed. Claim 1, lines 10-11 recite "on the one hand, and in that", which is confusing as to the structure the applicant is trying to claim. Claim 1, line

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11 recites "its ends", which is unclear as to if applicant is referring to new ends or the same ends as the two lateral ends. Claim 1, line 12 recites "the high retention of the mask", which is unclear as to how applicant defines high retention. Claim 1, lines 13-14 recites "other accessories", which is unclear as to what structure the applicant is trying to claim. Claim 2, line 3 recites "then" and line 6 recites "lastly", which makes it unclear as to if applicant is trying to claim a method step or apparatus. Claim 3, line 2 recites "any respiratory mask shells", which makes it unclear as to what structure the applicant is trying to claim. Claim 3, line 2 recites "whatever their size", which makes it unclear as to what structure the applicant is trying to claim. Claim 5, line 2 recites "made by thermoforming", which makes it unclear as to if applicant is trying to claim method of making in an apparatus claim. Claim 5, line 3 recites "any other material having similar properties", which makes it unclear as to what structure the applicant is trying to claim. Claim 6, lines 2-6 recite "the mounting of respiratory mask shells (7) that are custom-built by an acquisition procedure in three dimensions ("3D"), digital or non-digital, recording the reliefs and the depressions of the patient's face, and used for making, by means of a digitally-controlled machining system, a mold representing the inner or outer shell print". It appears applicant is trying to claim method of making in an apparatus claim. Claim 7, lines 3-4 recite "means of a step-by-step digitally-controlled machining system". It is unclear if applicant is trying to invoke the sixth paragraph of 35 U.S.C. 112.

14. Claim 1 recites the limitation "the shell (7)" in line 5. There is insufficient antecedent basis for this limitation in the claim. Claim 1 recites the limitation "the upper

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portion of the hub" in line 11. There is insufficient antecedent basis for this limitation in the claim. Claim 1 recites the limitation "the immobilization strap" in line 10. There is insufficient antecedent basis for this limitation in the claim. These are just a few examples of where there is insufficient antecedent basis for a limitation in a claim. More can be found throughout the claims, which should be corrected.

Claim Rejections - 35 USC § 101

15. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

16. The claimed invention is directed to non-statutory subject matter. Claim 1, line 9 recites "positioned around the head", which should be changed to --adapted to be positioned around the head--.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Correa et al. (6,119,694) in view of Lovell et al. (7,219,669 B1).

As to claim 1, Correa discloses a device for retaining a respiratory mask (14, Fig. 1) adapted to be used mainly in the field of non-invasive mechanical ventilation of airways (Fig. 1), whether in a hospital, at home or in any other location where non-invasive mechanical ventilation is used ("positive pressure device" A) (Fig. 1), this device has a hub ("first portion" 108) (Fig. 4) for receiving the shell first uninflated portion 104, Fig. 5) of the mask, such that the hub has at each of its two lateral ends ("a first portion" 118) (Fig. 4), fixing elements ("strap connectors" 50) (Fig. 1), having an articulation (point of connection of "strap connectors" 50) with a balance point on which are two laterally clipped right ("distal end" 124) (Fig. 4) and left ("distal end" 114) fins on which are fixed straps ("first headgear member" 20 and "second rearward lateral arm" 34) (Fig. 2) of the harness positioned around the head (Fig. 2), as well as the immobilization strap ("support strap" 54) (Fig. 2) for holding the patient's mouth closed (Fig. 2), on the one hand, and in that the upper portion of the hub is constituted of a strap ("support straps" 16 and 18) (Fig. 1) fixed at its ends and arranged to ensure the high retention of the mask so as to avoid frontward tilting during a substantial tension caused by the air inlet pipes ("conduit receptor" 19 and "conduit" 10) (Fig. 1) of the mask and other accessories ("positive pressure device" A) (Fig. 1) connected to the feed circuits. Regarding the clipped fins, Correa had the same structure as the applicant so Correa's element ("distal end") 124 is broadly being considered as the clipped fins. Correa is silent regarding that the fixing elements ("strap connectors" 50) (Fig. 1) are of the simple and fast unfastening snap-fastener type. However, Lovell teaches fixing elements ("connection points" 16 and 18) (Fig. 1A) are of the simple and fast

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unfastening snap-fastener type (Col. 6, ll. 9-16). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Correa's fixing elements ("strap connectors" 50) (Fig. 1), with the simple and fast unfastening snap-fastener type fixing elements, as taught by Lovell, for the purpose of providing an easy way of detaching the straps.

As to claim 2, Correa discloses that the hub is constituted of three affixed elements; first an upper veil ("gas deflector" 76) (Fig. 4) with two lateral extensions ("wings" 86 and 88) (Fig. 4) for fixing the harness (Fig. 4), an intermediary veil ("stem" 78) (Fig. 4) receiving the mask shell inserted through the base ("air opening" 74) (Fig. 4) and positioned in an L-shaped groove (defined by "wings" 86 and 88) (Fig. 4) along the base of the outline ("central orifice" 68) (Fig. 4) and, a peripheral contact lip ("second inflated portion" 106) (Fig. 5A) adapted to take support on the patient's skin (Fig. 5A). Correa is silent regarding that the intermediary veil ("stem" 78) (Fig. 4) is supple and elastic. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified Correa's intermediary veil to be of supple and elastic material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

As to claim 3, Correa's nasal mask discloses that the hub is arranged so as to be capable of adapting to any respiratory mask shells, whatever their size due to the hub's movable straps that conform to the patient's face, however large and thus can accommodate a larger or smaller mask shell (18, 16, Fig. 4) (Col. 3, ll. 50-53).

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As to claim 4, the modified Correa's nasal mask has a hub (first portion 108, Fig. 4), but lacks detail regarding that the hub is made of medical quality silicone enabling a long-term use. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified Correa's hub to be of medical quality silicone enabling a long term use, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

As to claim 5, the modified Correa's nasal mask discloses a hub (first portion 108, Fig. 4) and fins (distal ends 124, 114, Fig. 4), but lacks detail regarding that the hub and fins are made by molding. However, Lovell teaches molding parts of a nasal mask (Col. 4, ll. 28-31). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to fabricate the modified Correa's first portion and distal ends by molding, as taught by Lovell, since molding is a well know manufacturing procedure and it appears that the modified Correa's device would perform equally well with the molding first portion and distal ends.

19. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Correa et al. in view of Lovell et al. in further view of Maston (5,666,948).

As to claim 6, the modified Correa's nasal mask has a hub (first portion 108, Fig. 4) for mounting respiratory masks (14, Fig. 1, 4), but is silent regarding that the hub is designed to allow for the mounting of respiratory mask shells that are custom-built by an acquisition procedure in three dimensions (3D). However, Maston teaches that the hub ("external nare impression") (Col. 13, ll. 21) is designed to allow for the mounting (Col.

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13, ll. 20-21) of respiratory mask shells ("internal nare impression") (Col. 13, ll. 20) that are custom-built by an acquisition procedure in three dimensions (3D) (Col. 13, ll. 44-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the modified Correa's hub with a hub to be designed to allow for the mounting of respiratory mask shells that are custom-built by an acquisition procedure in three dimensions (3D), as taught by Maston, for the purpose of providing better fit and comfort for the user. The modified Correa's mask is silent regarding recording the reliefs and the depressions of the patient's face. However, Maston teaches recording the reliefs and the depressions of the patient's face (Col. 13, ll. 8-13) (Col. 13, ll. 44-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Correa's hub to be designed to record the reliefs and the depressions of the patient's face, as taught by Maston, for the purpose of providing better comfort for the user. The modified Correa's mask has a hub (first portion 108, Fig. 4), but is silent regarding making, by means of a digitally-controlled machining system, a mold representing the outer shell print. However, Maston teaches making, by means of a digitally-controlled machining system, a mold representing the outer shell print (Col. 13, ll. 8-13) (Col. 13, ll. 44-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the modified Correa's hub of the nasal mask to make, by means of a digitally-controlled machining system, a mold representing the outer shell print, as taught by Maston, for the purpose of providing a better fit for the user.

As to claim 7, the modified Correa's nasal mask discloses that the mask shell used is made by modeling the digital file that is obtained (Maston Col. 13, ll. 50-52) by means of a computer-assisted design software (Maston Col. 13, ll. 50-52) to make a mold (Maston Col. 13, ll. 50-54) by means of a step-by-step digitally-controlled machining system (Maston Col. 13, ll. 50-60), which makes it possible to form the shell by thermoforming a sheet of synthetic material (Maston Col. 13, ll. 50-60).

As to claim 8, the modified Correa's nasal mask discloses that the computer-assisted design software (Col. 13, ll. 48-50) is arranged to automatically take into account the specific morphology of each facial shape (Col. 13, ll. 50-54).

As to claim 9, the modified Correa's nasal mask discloses that the mask shell is made by transferring the digital file for making the masks (Col. 48-54). The modified Correa's nasal mask lacks detail regarding transferring the digital file to the memory of a standard home computer equipped with a graphics cord and a modem, then transmitted via the Internet, to a file exploitation site. Re claim 9, the claimed phrase "transferring the digital file to the memory of a standard home computer equipped with a graphics cord and a modem, then transmitted via the Internet, to a file exploitation site" is being treated as a product-by-process limitation and since it has been held that a product-by-process limitation is not construed as being limited to the product formed by the specific process recited, therefore, even though the modified Correa's nasal mask is silent as to the process used to transfer the digital file, it appears that the modified Correa's product would be the same or similar as that claimed, especially since both applicant's product and the prior art product is made of synthetic material.

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20. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Correa et al. in view of Lovell et al. in further view of Stenzler et al. (2003/0200970 A1).

As to claim 10, Correa discloses that the mask shell is connected to a pressurized gas-feeding pipe ("conduit" 10) (Fig. 1) (Col. 2, ll. 43-45). The modified Correa's nasal mask is silent regarding that the conduit is connected by means of an articulated coupling having a ball-and-socket joint. However, Stenzler teaches that the conduit ("breathing hose" 20) (Fig. 1) (Page 2, ¶ 26) is connected by means of an articulated coupling having a ball-and-socket joint ("breathing end" 72 and "passageway end" 76) (Fig. 2) (Page 3, ¶ 37). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the modified Correa's nasal mask assembly with a conduit that is connected by means of an articulated coupling having a ball-and-socket joint, as taught by Stenzler, for the purpose of providing less tension on the mask to provide comfort to the user.

21. Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Correa in view of Lovell/Stenzler in further view of Luetngen et al. (2002/0117229 A1).

As to claim 11, the modified Correa's coupling discloses that the articulated coupling (Stenzler "breathing end" 72 and "passageway end" 76) (Fig. 2) (Page 3, ¶ 37) comprises a female ball-and-socket joint (Stenzler "breathing end" 72) (Fig. 2) (Page 3, ¶ 37) at the end of the gas-feeding pipe (Stenzler "breathing hose" 20) (Fig. 1) (Page 2, ¶ 26). The modified Correa's coupling is silent regarding a male ball-and-socket joint mounted on the respiratory mask. However, Luetngen teaches a male ball-and-socket joint (a third "bead" 26 added to the bottom of Fig. 5 would create a male ball-and-

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socket joint) (Fig. 5 and 6) (Page 2, ¶ 24, ll. 18-19). Although the male ball and socket joint is not mounted on a respiratory mask, by replacing the connection of Correa with that of Luetngen, it would have been an obvious design consideration to one of ordinary skill in the art at the time the invention was made to modify the modified Correa's coupling to place the male ball and socket joint of Luetngen on the respiratory mask of Correa, which would perform equally as well. The modified Correa's coupling is silent regarding a substantially cylindrical joint that can be funnel-shaped to allow for connecting and disconnecting couplings having a varying diameters. However, Luetngen teaches a substantially cylindrical joint (middle "bead" 26 of a three bead connection) (Fig. 5) that can be funnel-shaped (Fig. 5) to allow for connecting and disconnecting couplings having a varying diameters (Page 2, ¶ 24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Correa's coupling to include a substantially cylindrical joint that can be funnel-shaped to allow for connecting and disconnecting couplings having a varying diameters, as taught by Luetngen, for the purpose of providing an easy assembly.

As to claim 12, the modified Correa's coupling discloses that the articulated connection (Stenzler "breathing end" 72 and "passageway end" 76) (Fig. 2) (Page 3, ¶ 37) comprises at least one intermediary cylindrical coupling sleeve (Luetngen middle "bead" 26 of three beads) (Fig. 5) comprising two spherical elements (Luetngen "smaller end" 36 and "larger end" 34) (Fig. 3), male and female respectively (Luetngen Fig. 3).

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As to claim 13, the modified Correa's coupling is silent regarding that the clearance of the ball-and-socket joints of the articulated connection is limited by an annular lock pin of the male portions taking support on an inner annular abutment of the female portions so as to prevent the generally cylindrical ducts butt-joined in the ball-and-socket joints from being obstructed, even partially. However, Luetngen teaches the clearance (amount the ball and socket joints can rotate Fig. 5) of the ball-and-socket joints of the articulated connection is limited by an annular lock pin ("tapered neck area" 38) (Fig. 3) of the male portions taking support on an inner annular abutment (end of "smaller end" 36) (Fig. 4) of the female portions so as to prevent the generally cylindrical ducts butt-joined in the ball-and-socket joints from being obstructed, even partially (Fig. 5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Correa's coupling to include that the clearance of the ball-and-socket joints of the articulated connection is limited by an annular lock pin of the male portions taking support on an inner annular abutment of the female portions so as to prevent the generally cylindrical ducts butt-joined in the ball-and-socket joints from being obstructed, even partially, as taught by Luetngen, for the purpose of providing an open airway for the user.

As to claim 14, the modified Correa's coupling discloses that the articulated connection is designed to allow for a vertical clearance angle greater than 90° (Luetngen Fig. 5).

As to claim 15, the modified Correa's coupling discloses that the female ball-and-socket joint (Stenzler "breathing end" 72) (Fig. 2) (Page 3, ¶ 37), the male ball-and-

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socket joint (Luettgen a third "bead" 26 added to the bottom of Fig. 5 would create a male ball-and-socket joint) (Fig. 5 and 6) (Page 2, ¶ 24, ll. 18-19), and the intermediary coupling sleeve (Luettgen middle "bead" 26 of three beads) (Fig. 5) are each made of a single piece arranged to enable the mounting of the ball-and-socket joints by forcible nesting (Luettgen Fig. 5) (Page 2, ¶ 24).

22. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Correa in view of Lovell/Stenzler/Luettgen in view of Elder (2002/0167167 A1).

As to claim 16, the modified Correa's coupling has a female ball-and-socket joint (Stenzler breathing end 72, Fig. 2) (Page 3, ¶ 37), the male ball-and-socket joint (Luettgen a third "bead" 26 added to the bottom of Fig. 5 would create a male ball-and-socket joint) (Fig. 5 and 6) (Page 2, ¶ 24, ll. 18-19), and the intermediary coupling sleeve (Luettgen middle "bead" 26 of three beads, Fig. 5), but is silent regarding that the female ball-and-socket joint, the male ball-and-socket joint, and the intermediary coupling sleeve are made of molded plastic material. However, Elder teaches that the female ball-and-socket joint, the male ball-and-socket joint, and the intermediary coupling sleeve are made of molded plastic material (Page 1, ¶ 9, ll. 3-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Correa's coupling such that the female ball-and-socket joint, the male ball-and-socket joint, and the intermediary coupling sleeve are made of molded plastic material, as taught by Elder, for the purpose of reducing the cost.

Conclusion

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Esmailzadeh (5,873,363) to a breathing apparatus with chin and head straps, Jestrabek-Hart (6,470,886 B1) to a continuous positive airway pressure headgear with many straps and a conduit, Wilkie et al. (2003/0172938 A1) to a mask with many straps and an accompanying conduit, Soloman et al. (5,645,539) to a nasal mask with a ball and socket connection, Hesselin et al. (5,975,588) to a ball and socket coupling, Christianson (6,648,376 B2) to multiple ball and socket joints, and Treutelaar (4,373,523) to a helmet with multiple straps including a chin strap. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL T. YOUNG whose telephone number is (571)270-1481. The examiner can normally be reached on mon-thurs 7 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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